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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,942	06/21/2001	Juha Punnonen	02-031910US	4876

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EXAMINER	
CHEN, LIPING	

ART UNIT	PAPER NUMBER
1632	10

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,942	PUNNONEN ET AL.	
	Examiner	Art Unit	
	Liping Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-103* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-48, 62-66, 74-79, 93 and 94 drawn to an isolated or recombinant nucleic acid comprising a polynucleotide sequence that promotes expression of an operably linked transgene, a vector, and a method of production of a polypeptide from a cell culture, and a kit, classified in 536, subclass 23.1 or class 435, subclass 320.1 or 69.1.

II. Claims 49-50, drawn to a composition that comprising the cleavage products of recombinant nucleic acids, classified in 536, subclass 23.1.

III. Claims 51-52, drawn to a composition that comprising the elongation products of recombinant nucleic acids, classified in 536, subclass 23.1.

IV. Claims 53-56, 58, and 59, drawn to a method of producing a modified nucleic acid *in vitro*, classified in class 435, subclass 455.

V. Claims 53-55, 57-59, drawn to a method of producing a modified nucleic acid *in vivo*, classified in 514, subclass 44.

VI. Claims 53, 60, 61, and 67, drawn to a method of production of a nucleic acid library, a nucleic acid library, and a population of cells comprising the library, classified in 435, subclass 91.1.

VII. Claims 68-74, 82, and 84-92, drawn to a pharmaceutical composition comprising nucleic acid or a vector, and a method of production of a polypeptide from a cell *in vivo*, classified in class 514, subclass 44.

VIII. Claims 74, 80, and 81, drawn to a method of production of polypeptide from a transgenic animal, classified in class 800, subclass 4.

IX. Claims 74, 82, and 83, drawn to a method of production of a polypeptide from a cell *ex vivo*, classified in class 424, subclass 93.21.

X. Claims 95-97, drawn to a database comprising one or more character strings corresponding to a polynucleotide sequence selected from SEQ ID NO:1-18, classified in class 360, subclass 135.

XI. Claims 98-103, drawn to a method for manipulating a sequence record in a computer system, classified in class 702, subclass 20.

The inventions are distinct, each from the other because:

Invention I and any of inventions II-XI are mutually exclusive and independent. The method of producing polypeptide in cell culture of invention I is not needed for the implementation of the DNA cleavage product of invention II, the DNA elongation product of invention III, method of producing a modified nucleic acid of invention IV and V, method of production of a nucleic acid library of invention VI, a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention II and any of inventions III-XI are mutually exclusive and independent. The DNA cleavage product of invention II is not needed for the implementation of the DNA elongation product of invention III, a method of producing a modified nucleic acid of invention IV and V, a method of production of a nucleic acid library of invention VI, a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention III and any of inventions IV-XI are mutually exclusive and independent. The DNA elongation product of invention III is not needed for the implementation of method of producing a modified nucleic acid of invention IV and V, a method of production of a nucleic acid library of invention

VI, a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention IV and any of inventions V-XI are mutually exclusive and independent. The method of producing a modified nucleic acid in vitro of invention IV is not needed for the implementation of method of producing a modified nucleic acid in vivo of invention V, method of production of a nucleic acid library of invention VI, a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention V and any of inventions VI-XI are mutually exclusive and independent. The method of producing a modified nucleic acid in vivo of invention V is not needed for the implementation of method of production of a nucleic acid library of invention VI, a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention VI and any of inventions VII-XI are mutually exclusive and independent. The method of production of a nucleic acid library of invention VI is not needed for the implementation of a pharmaceutical composition of invention VII, a method of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention VII and any of inventions VIII-XI are mutually exclusive and independent. The method of production of a polypeptide in vivo of invention VII is not needed for the implementation of a method

of production of a transgenic animal of invention VIII, a method of production a polypeptide ex vivo of invention IX, a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention VIII and any of inventions IX-XI are mutually exclusive and independent. The method of production a polypeptide ex vivo of invention IX is not needed for the implementation of a database of invention X or a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Invention IX and any of inventions X-XI are mutually exclusive and independent. The database of invention X is not needed for the implementation of a method of manipulating a sequence record in a computer system of invention XI, and vice versa. Each of the methods requires a separate and materially different protocol.

Because these inventions are distinct for the reasons given above, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is

elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

As indicated above, applicant is required to elect one group for restriction practice. Should applicant choose to do so, any sequences fully embedded in the elected sequence will also be examined. Applicant is required to identify any such embedded sequences and there cannot be any overlap with other sequences not in the elected sequence.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632
June 27, 2002

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~/630